



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL -8 1997

Re: NASCOBAL™
Docket No. 97E-0076

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

RECEIVED

JUL 16 1997

PATENT EXTENSION
A/C PATENTS

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,724,231 filed by Natestch Pharmaceutical Company, Inc. under 35 U.S.C. § 156. The human drug product claimed by the patent is NASCOBAL™ (cyanocobalamin), which was assigned New Drug Application (NDA) No. 19-722.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that it **does not** represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990). For example, BETALIN 12, CORBAVITE, CYANOCOBALAMIN, RUBRAMIN, RUVITE, and VIBISONE contain the same active ingredient as in NASCOBAL™, cyanocobalamin (see attachment).

The NDA was approved on November 5, 1996, which makes the submission of the patent term extension application on January 3, 1997, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

A handwritten signature in black ink, reading "Ronald L. Wilson". The signature is fluid and cursive, with the first name "Ronald" being the most prominent.

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

Attachment

cc: Gerald T. Bodner, Esq.
Hoffman & Baron
350 Jerico Turnpike
Jerico, NY 11753

APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. This volume and accompanying first supplement are current through January 31, 1997.

17TH EDITION



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DATABASE MANAGEMENT

1997

PRESCRIPTION DRUG PRODUCT LIST

3-85

COSYNTROPIN

INJECTABLE; INJECTION
CORTROSYN
+ ORGANON

0.25MG/VIAL

N16750 001

10%

N06927 001

CROMOLYN SODIUM

AEROSOL, METERED; INHALATION
INTAL
+ FISON

0.8MG/INH

N18887 001
DEC 05, 1985

10%

N87204 001

N09112 003

CAPSULE; INHALATION
INTAL
+ FISON

20MG

N16990 001

CAPSULE; ORAL
GASTROCROM
+ MEDEVA

100MG

N19188 001
DEC 22, 1989

CONCENTRATE; ORAL
GASTROCROM
+ MEDEVA

100MG/5ML

N20479 001
FEB 29, 1996

0.5MG/INH

N19722 001
NOV 05, 1996

SOLUTION; INHALATION
CROMOLYN SODIUM
DEY

10MG/ML

N74209 001
APR 26, 1994

0.1MG/ML
1MG/ML

AN
INTAL
+ FISON

10MG/ML

N18596 001
MAY 28, 1982

CYANOCOBALAMIN
ELKINS SINN
FUJISAWA

1MG/ML
0.1MG/ML
1MG/ML
1MG/ML
1MG/ML

N83013 001
N83064 001

SOLUTION/DROPS; OPHTHALMIC
CROLOM
+ BAUSCH AND LOMB

4%

N74443 001
JAN 30, 1995

0.1MG/ML
0.1MG/ML
1MG/ML
1MG/ML
1MG/ML
1MG/ML

N80515 002
N80557 002
N80564 001
N80737 001
N87551 001
FEB 29, 1984

SPRAY, METERED; NASAL
NASALCROM
+ FISON

5.2MG/SPRAY

N18306 001
MAR 18, 1983

0.1MG/ML
0.1MG/ML
1MG/ML
1MG/ML
1MG/ML
1MG/ML
1MG/ML
1MG/ML

N80573 002
N83120 001
N80573 001
N83120 002
N80554 001
N80554 002
N06799 004
N80570 002

INJECTABLE; INJECTION
CUPRIC CHLORIDE IN PLASTIC CONTAINER
+ ABBOTT
EQ 0.4MG COPPER/ML

CUPRIC CHLORIDE

CYANOCOBALAMIN

GEL, METERED; NASAL
NASCOBAL
+ NASTECH

INJECTABLE; INJECTION
CORAVITE
STERIS

CYANOCOBALAMIN

ELKINS SINN
FUJISAWA
HOECHST MARION RSSL
LUITPOLD
SOLOPAK

STERIS

WYETH AYERST

ROBRAMIN PC
+ SQUIBB

ROVITE
SAVAGE LABS

